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and the Class*

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

TED DAVISON, WILLIAM GOULD, AND
RAY LENCI, Individually And
On Behalf of All Others Similarly Situated,

Plaintiffs,

vs.

VENTRUS BIOSCIENCES, INC., DR.
RUSSELL H. ELLISON, and DAVID J.
BARRETT,

Defendants.

Case: 13-CV-3119-RMB

HON. JUDGE RICHARD M.
BERMAN

**CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

1. Lead Plaintiffs Thomas P. and Doris C. Alderson, (the “Aldersons” or “Plaintiffs”) bring this federal class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf those who purchased or otherwise acquired Ventrus Biosciences, Inc. (“Ventrus” or the “Company”) securities between December 17, 2010 and June 25, 2012, inclusive (the “Class Period”) seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Plaintiffs allege the following based upon the investigation of Plaintiffs’ counsel, which included a review of SEC filings by Ventrus, regulatory filings and reports, securities analysts’ reports and advisories about the Company, press releases and other public statements issued by the Company, media reports about the Company, and discussions with witnesses with knowledge of the allegations herein. Plaintiffs believe that substantial additional evidentiary support will exist for these allegations after a reasonable opportunity for discovery.

Confidential Witnesses

3. CW1 is the former Chief Medical Officer of Ventrus who worked for the Company in this capacity from June 2007 to March 2009. According to CW1, he was one of three people working at Ventrus at the time, and the other two were Defendant Ellison and Vice President of Clinical Operations Dr. John Dietrich (“Dietrich”). The information attributable to CW1 is based upon his personal experiences and observations working together with Defendant Ellison at Ventrus.

4. CW2 has been a Clinical Research Associate with LCH Clinical Research LLC since June 2005, and worked on the Phase III trial of iferanserin (“VEN 309”) under a contract with Armonia Clinical Research, a contract research organization (“CRO”) run by Christina DiArchangelo Puller, an employee of Ventrus. CW2 has fifteen years of experience working on

clinical trials. The information attributable to CW2 is based upon his/her role as a clinical research associate on the VEN 309 trials from November 2011 until the end of June 2012 visiting clinical trial sites and monitoring patients.

5. CW3 was an intern at National Securities Corporation ("National Securities") from September 2010 to February 2011. National Securities was the co-lead underwriter for the IPO. CW3, along with approximately 14 other interns worked in shifts to solicit investments in Ventrus' IPO by making calls to potential investors. The information attributable to CW3 is based upon his/her person responsibilities during the internship with National Securities and his/her physical presence in National Securities meetings regarding the Ventrus IPO.

OVERVIEW

6. Ventrus is a developmental stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence. Incorporated in October 2005 under the name South Island Biosciences, Inc., the Company did not begin its operations until April 2007 when it acquired the licenses to VEN 307 and 308 with a loan from Lindsay A. Rosenwald ("Rosenwald") and/or his company, Paramount Biosciences and changed its name to Ventrus Biosciences, Inc. In March of the following year, with an additional loan from Rosenwald and/or Paramount Biosciences, Ventrus acquired the license to VEN 309.

7. According to CW1, Ventrus' former Chief Medical Officer who worked for the Company from June 2007 up until the time Ventrus acquired the license for VEN 309, he was one of only three people working for Ventrus during this time period. At the time CW1 resigned in March 2009, CW1 stated that Ventrus was limping along and could not begin any drug trials because the Company did not have any money.

8. VEN 309 provided the perfect conduit to infuse capital into a stagnant company. Ifersanerin ointment (VEN 309) was developed by Sam Amer, Ph. D., a former director of research and development at Bristol-Myers Squibb Company, as a treatment for hemorrhoids. Hemorrhoids are characterized by inflammation and swelling of veins around the anus or lower rectum, and can cause bleeding, itchiness, pain and difficulty defecating. According to Ventrus, hemorrhoids affects approximately 12.5 people in the United States, and while some prescription drugs are commonly used in the United States for hemorrhoids and combination products such as Preparation H are available for temporary relief of hemorrhoid symptoms, no prescription drugs have yet been approved by the FDA that address the cause of hemorrhoids. As such, an enormous marketing opportunity existed, and still exists, for an FDA approved treatment of hemorrhoids. According to CW1, this is “what you wanted” from a pharmaceutical standpoint, because it was based on an original chemical.

9. Because Ventrus had no money to finance the development of its licensed drugs on its own and could not even afford to pay employees, the Company needed investors to pay its creditors, pay its executives’ salaries, hire employees, and continue as a going concern. The market void that VEN 309 could fill was exceptionally enticing to investors, as an FDA approved hemorrhoid treatment would produce a mountain of revenue for years to come. VEN 309 had another unique characteristic that attracted investors as well. In contrast to VEN 307 and VEN 308, Defendants conveyed to the public that VEN 309 was ready for its Phase III trial due to its “successful” Phase IIB studies conducted in Germany; therefore, investors could not only be comforted by the drug’s previous trial experience, but could also expect to see returns on their investment in a reasonable time period. As explained by Defendant Ellison in a June 25, 2012 conference call, VEN 307 and VEN 308 were much further behind than VEN 309. Thus,

VEN 307 and VEN 308 could never have raised enough investor interest to finance their development.

10. On December 17, 2010, Ventrus, manned by only two employees—the Chief Executive and Medical Officer, Defendant Ellison and the Chief Financial Officer, Defendant Barrett—and a part-time consultant, Dr. Dietrich, commenced its Initial Public Offering (“IPO”) by filing a Prospectus with the SEC on Form 424B4 (the “IPO Prospectus”). In connection with the IPO, Ventrus offered 2.9 million shares of common stock at \$6.00 per share.

11. With help from co-underwriter National Securities, the IPO successfully raised gross proceeds of approximately \$16.1 million by touting VEN 309. Ventrus’ IPO required a second underwriter because National Securities was indirectly controlled by Rosenwald, Ventrus’ largest shareholder and leading creditor, as a result of a purchase transaction that took place shortly before the offering. According to CW3, an intern who called wealthy investors to solicit interest in Ventrus’ IPO, Rosenwald made a presentation in front of about a hundred people at National Securities and spoke specifically about iferanserin topical cream.

12. Despite being described by Ventrus as the Company’s “lead product” in their Prospectus and Ventrus’ conflicted underwriter touting the high likelihood its FDA approval, VEN 309 had an unproven track record. In 1998, Sam Amer (“Amer”) licensed an early stage of the product to Tsumura, a Japanese pharmaceutical company. Tsumura conducted over 350 pre-clinical and six clinical studies on the drug, but ultimately discontinued its development and turned the product back over to Amer. Amer then conducted his own testing of the drug—a double-blind, placebo controlled, multi-center confirmatory non-pivotal Phase IIB/Phase III study in Germany—that led to Amer licensing iferanserin to Novartis Pharmaceuticals in 2003. Novartis also conducted various toxicology and metabolite studies on the drug over the next

couple of years, but then, like Tsumura, abandoned its development efforts and returned the drug back to Amer.

13. CW1 explained that there were not many patients in Amer's self-financed Phase IIB/Phase III study in Germany. Only 121 patients were studied for the Germany Phase IIB tests in contrast to the 603 studied in the Phase III trials and the 1500 required by the FDA for a chronic use drug. Furthermore, the endpoints of Amer's Phase IIB study were based on the patients' own assessments of reduction in bleeding (primary endpoint) and pain, itchiness, and other sensations (secondary endpoints), which were far more subjective and easier to meet than the Phase III endpoints that required a complete cessation of bleeding, pain, itchiness, etc. Thus, while CW1 stated that potential buyers "[couldn't] say it didn't work," the Phase IIB study was not reflective of the high hurdles VEN 309 would have to overcome in the Phase III trials. Amer therefore had the ability to use these old 2003 test results to, as CW1 explained, "peddle the product" to pharmaceutical companies in the market for a game-changing drug. Despite the fact that the small testing groups and subjective endpoints used in Amer's studies could not produce a reliable gauge of the efficacy of VEN 309, the December 17, 2010 Prospectus touted the results, stating, "Phase II studies consistently demonstrate that iferanserin treatment significantly reduces hemorrhoidal symptoms of bleeding, itching and pain..."

14. In addition to touting the earlier test results, the IPO Prospectus also emphasized that the Company had submitted a Special Protocol Assessment ("SPA") with the FDA and expected to complete the SPA process by the end of the first quarter of 2011. CW1 explained that SPAs give investors the false impression that the FDA will likely approve the drug, when, in fact, completing an SPA has nothing to do with approval of the drug, but rather that the FDA will simply accept the study as valid protocol. CW1 also explained that the drawback to submitting

the SPA was that once FDA approved the VEN 309 SPA application, Ventrus would be locked into that protocol approved by the FDA. In the end, the SPA filed by Ventrus was simply a ploy to lure investors to their IPO by implying that the FDA would likely approve VEN 309, because on June 22, 2011, Ventrus issued a press release explaining that they had withdrawn their SPA application with the FDA and abandoned any further plan to have the FDA approve their protocol. Thus, by telling investors that Ventrus would seek SPA approval from the FDA but then pulling the application six months later, Ventrus received the benefit of attracting investor support for the IPO while avoiding the pitfall of locking themselves in the FDA's approved protocol.

15. Ventrus made two additional offerings to the public during the Class Period that raised, collectively with the IPO, over \$70 million. On July 14, 2011, approximately seven months after Ventrus' first offering, the Company filed another Prospectus ("Prospectus II"), which accompanied an offering of 4.5 million shares of Ventrus stock at \$10.00 per share. Then, on May 30, 2012—*less than one month before* the Company announced the complete failure of VEN 309's Phase III trials—Ventrus filed a third Prospectus ("Prospectus III"), which accompanied an offering of 948,378 shares at \$10.24 per share. These additional offerings—particularly the third offering that took place just before the Company revealed the previously concealed true facts regarding, *inter alia*, the ineffectiveness of VEN 309—illustrate the desperation of Defendants to collect more revenue while investors still believed VEN 309 to be a viable treatment for hemorrhoids. The prospectus accompanying each offering touted Ventrus' "lead product" VEN 309 and its successful Phase IIb/Phase III trials and investors flocked to each offering.

16. Each of Ventrus' three Prospectuses, as well as Defendants' other public

statements and filings made throughout the Class Period, contained untrue statements of material facts and omitted facts necessary in order to make the statements about Ventrus and its business operations and future prospects, including *inter alia*, the efficacy of VEN 309, the purported success of the VEN 309's Phase IIB testing, and the Company's intentions to drop the drug's SPA, in light of the circumstances under which the statements were made, not misleading.

17. Moreover, Ventrus included incentive bonuses for Defendants Ellison and Barrett that were tied exclusively to the Company's market capitalization. Under these arrangements, Ellison and Barrett could achieve a bonus of \$250,000 in the event the Company's market capitalization exceeded \$100 million—which happened in August 2011 and resulted in prompt payment of bonuses to Ellison and Barrett in September 2011—and \$500,000 in the event the market capitalization exceeded \$250 million. As these bonuses were not tied to the success of VEN 309 or any of the Company's other candidates, but rather solely to the stock price, Defendants were incentivized to mislead the marketplace as to the viability of VEN 309.

18. With regard to the money spent on the VEN 309 Phase III trial, Ventrus did not finance the study like a company expecting positive results from the drug. According to CW2, in all his/her 15 years of experience working on clinical trials, the VEN 309 Phase III test stood out from all the others because of the way it was managed. First, despite all the capital raised in the IPOs, Ventrus was "cheap" when it came to the VEN 309 trials. Ventrus would not pay its clinical sites on time, if at all, leading to many sites asking CW2 if they would even get paid at all. Second, Ventrus refused to pay for standard incidental procedures encountered. For example, one of the exclusions to participation in the trials was for cancer. As a result, Ventrus performed colonoscopies to assure none of the test participants had cancerous polyps. Ventrus, however, routinely refused to pay for the removal of polyps in patients, even though the doctors

explained that this was part of the “standard of care” owed to the patients. The only exception to this was a single instance where polyps were removed from a single patient one time, after intervention by a doctor.

19. On June 25, 2012, less than one month after the completion of the Company’s third offering of shares to the public, Ventrus issued a press release, also filed on Form 8-K with the SEC, in which the Company announced that it would shut down the development of VEN 309. Despite the purported universal success evidenced by Amer’s Phase IIB/Phase III VEN 309 tests in Germany, the Phase III trials conducted by Ventrus’ contracted CROs resulted in 603 patients—*every single participant* in the VEN 309 Phase III trials—failing to meet the endpoints for cessation of bleeding, itching and pain assessed in the trials.

20. CW2 stated that he/she had also never experienced a clinical trial being cancelled in the manner that VEN 309 was shut down. CW2 said that in June 2012 he/she had been sitting in his/her office working on reports when he/she learned of the Ventrus press announcement regarding the VEN 309 adverse test results. Within minutes he/she received calls from the testing sites and an email from Ventrus shutting down the whole operation. CW2 said that ordinarily the trials take up to two years to complete because they also entail treatment, follow-up and monitoring of patients. Also, CW2 had been contracted for 2 studies of the drug, but Ventrus shut the trials down after the first trial.

21. VEN 309 was never on a track to development and manufacture. VEN 309 simply provided a lifeline of investor support for a company struggling to survive and succeeded in raising tens of millions of dollars and ensuring that Defendants Ellison and Barrett received hefty salaries and stock-linked bonuses. Then, VEN 309 was promptly abandoned.

22. On June 25, 2012, when Ventrus issued a press release announcing that it would

completely halt the development of VEN 309, after the Phase III trials resulted in all 603 patients failing to meet the endpoints for improved bleeding, itching and pain assessed in the trials, Ventrus shares plummeted from \$12.26 on the previous trading day to just \$5.02, a devastating 59% decrease in Ventrus' stock value on unusually high trading volume.

JURISDICTION AND VENUE

23. The Securities Act claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the United States Securities and Exchange Commission ("SEC") [17 C.F.R. § 240.10b-5].

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

25. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). GMCR maintains its principal place of business in this District and many of the acts and practices complained of herein occurred in substantial part in this District.

26. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

Lead Plaintiff

27. Lead Plaintiffs Thomas P. and Doris C. Alderson, as set forth in their previously-filed certification [Case No. 1:13-cv-3429, Dkt. #10-1], incorporated herein by reference, purchased Ventrus securities at an artificially inflated price during the Class Period, and were

harmful when the price of Ventrus securities dropped as a result of the revelations of the truth at the end of the Class Period.

Defendants

28. Defendant Ventrus is a Delaware Corporation with its principal place of business located at 99 Hudson Street, 5th Floor, New York, New York 10013. Ventrus is a development stage specialty pharmaceutical company that focuses on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoidal disease, anal fissures and fecal incontinence. Ventrus' shares traded throughout the Class Period on the NASDAQ stock exchange under the symbol "VTUS."

29. Defendant Russell H. Ellison ("Ellison") has been the Chief Executive Officer and Chief Medical Officer of Ventrus since December 2010, when Ventrus completed its IPO. For the six months prior to the IPO, Ellison acted as a consultant to Ventrus. Ellison has also been the Chairman of the Board of Directors since January 2011. Ellison earned an annual salary of \$375,000 during the Class Period, notwithstanding stock options and performance bonuses. Ellison also earned a bonus of \$250,000 in August 2011 because the Company reached a market capitalization milestone of \$100 million. Ellison was also slated to earn a bonus of \$500,000 if the Company reached a market capitalization milestone of \$250 million. During the Class Period, Ellison signed and certified the Company's SEC filings, including Ventrus' annual report on Form 10-K and/or quarterly reports on Form 10-Q.

30. Defendant David J. Barrett ("Barrett") has been the Chief Financial Officer and Accounting Officer of Ventrus since December 2010, when Ventrus completed its IPO. For the six months prior to the IPO, Barrett acted as a consultant to Ventrus. Barrett earned an annual salary of \$250,000 during the Class Period, notwithstanding stock options and performance

bonuses. Barrett also earned a bonus of \$250,000 in August 2011 because the Company reached a market capitalization milestone of \$100 million. Barrett was also slated to earn a bonus of \$500,000 if the Company reached a market capitalization milestone of \$250 million. During the Class Period, Barrett signed and certified the Company's SEC filings, including Ventrus' annual report on Form 10-K and/or quarterly reports on Form 10-Q.

31. Collectively, Ventrus, Ellison, and Barrett are referred to as "Defendants."

**MATERIALLY UNTRUE & MATERIALLY MISLEADING STATEMENTS AND/OR
OMISSIONS DURING THE CLASS PERIOD**

32. Plaintiffs' allegations stem from Defendants' issuance of materially false and/or misleading statements and omissions during the Class Period contained in SEC filings, Company releases, and conference calls with analysts. These statements and omissions concealed true, adverse facts about, *inter alia*, the efficacy of VEN 309, Ventrus' lead drug candidate, and its likelihood of FDA approval.

33. On December 17, 2010, Ventrus commenced its IPO by filing the IPO Prospectus with the SEC on Form 424B4. In connection with the IPO, Ventrus offered 2.9 million shares of common stock at \$6.00 per share to raise gross proceeds of approximately \$16.1 million.

34. Among other things, the IPO Prospectus repeatedly misled investors as to the overall efficacy of VEN 309. For example, the IPO Prospectus stated:

[O]ur product, iferanserin ointment (VEN 309), has highly selective, antagonistic activity against peripheral 5-HT_{2A} receptors (5HT_{2A} > 5HT_{2C} >> 5HT_{2B}) involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-HT_{2A} receptor activity, *VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain.* We believe that the potential for side effects is likely to be limited because iferanserin is topically applied and iferanserin does not enter the brain to affect 5HT₂ CNS receptors, at the exposures seen with topical application. *In multiple clinical trials, iferanserin ointment significantly reduced bleeding, pain and itchiness compared to placebo with minimal adverse effects. As a result, we believe VEN*

309 to be more effective and/or less invasive than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only other currently validated treatment options.

[Emphasis added.]

35. The foregoing statements were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that VEN 309 did not, in fact, “improve[] the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain.” Defendants did not have any reliable data to demonstrate the drug’s efficacy, and were, at minimum, reckless in stating otherwise. Indeed, the “multiple clinical trials” Defendants reference that purportedly demonstrated “significantly reduced bleeding, pain and itchiness compared to placebo” all used such a small sample of participants that CW1, Ventrus’ former chief medical officer, said that “you can’t say it didn’t work.” Thus, Defendants’ touting of earlier testing misled investors as to VEN 309’s previous testing success and anticipated FDA approval. For these reasons, Defendants had no reason to “believe VEN 309 to be more effective and/or less invasive than the currently available conventional hemorrhoid topical therapies.”

36. The IPO Prospectus also touted the results of Phase I and II testing for VEN 309:

The Phase I studies in volunteers and the Phase II studies in patients demonstrated that iferanserin is well tolerated, and minimally absorbed. ***Phase II studies consistently demonstrate that iferanserin treatment significantly reduces hemorrhoidal symptoms of bleeding, itching and pain,*** and that the 0.5% concentration that we will be developing was superior to lower concentrations and to higher concentration (1%) in the comprehensive reduction of hemorrhoid symptoms.

[Emphasis added.]

37. These statements were false and/or misleading when made because Defendants knew and/or recklessly disregarded that VEN 309’s Phase II studies conducted by Amer, the

same person who was peddling VEN 309 to reap millions in licensing fees, did not “consistently demonstrate that iferanserin treatment significantly reduces hemorrhoidal symptoms of bleeding, itching and pain” because Phase II data was unreliable given the small sample sizes used.

38. The IPO Prospectus also stated:

Our lead product, Inferanserin [sic] (VEN 309) is a NCE for the topical treatment of hemorrhoids. *In multiple clinical studies in 359 patients, VEN 309 demonstrated good tolerability and no severe adverse events, and statistically significant improvements in bleeding, itchiness and pain.*

[Emphasis added.]

39. This statement was false and/or misleading when made because Defendants knew and/or recklessly disregarded that the “359 patients” were divided into so many studies that the results of the VEN 309 testing did not in fact “demonstrate[] good tolerability” nor did they produce “statistically significant improvements in bleeding, itchiness and pain.”

40. The IPO Prospectus further state, with regard to the success of Dr. Amer’s clinical studies:

We have licensed Iferanserin ointment (VEN 309) from Sam Amer & Co., Inc., or Amer, *who had developed VEN 309 through Phase II studies and up to readiness for Phase III studies in the U.S. and Europe.*

* * *

Dr. Amer’s company, Sam Amer & Co., Inc., or Amer, conducted a double-blind, placebo controlled, multi-center confirmatory non-pivotal phase III study in Europe. *After the successful completion of that study in 2003*, Novartis Pharmaceuticals licensed iferanserin from Amer to be part of its gastroenterology portfolio strategy.

[Emphasis added.]

41. These statements were materially false and/or misleading when made, as Defendants knew and/or recklessly disregarded that Amer’s testing in Germany had not brought VEN 309 “up to readiness for Phase III testing in the U.S. and Europe,” because Amer’s test

results were inconclusive due to the small sample size. Indeed, had Amer brought the VEN 309 Phase IIb/Phase III testing in Germany to “successful completion,” not only would VEN 309 demonstrated at least some modicum of efficacy in Ventrus’ Phase III testing, but Novartis likely would have never discontinued its development.

42. The IPO Prospectus also noted, regarding the reasons Tsumura and Novartis abandoned research on Iferanserin:

Also in 1998, the early stage product was licensed to Tsumura, a Japanese company. Tsumura conducted over 350 preclinical and six clinical studies, *but was not able to continue development due to financial difficulty* and returned the product to Dr. Amer....Novartis improved the iferanserin manufacturing processes and completed important toxicology and metabolite studies. *In 2005, Novartis’ lead gastroenterology product, Zelnorm® was experiencing increased FDA scrutiny on the safety of that product, which would ultimately lead to its eventual withdrawal from the market. We believe that with the impending loss of their lead gastroenterology product, Novartis decided to dissolve the gastrointestinal franchise. In 2005, Novartis returned iferanserin to Amer. According to Amer, no safety or clinical issues were ever communicated as reasons for the return.*

[Emphasis added.]

43. These statements were materially false and misleading when made because, if iferanserin ointment demonstrated the effectiveness in Amer’s purportedly “successful” phase II studies, Tsumura and Novartis would not have given the product license back to Amer, as it would have been too profitable. Thus, Defendants were at least reckless in informing investors that “no clinical issues were ever communicated as reasons for the return.”

44. Further, the IPO Prospectus explained the Company’s plans to seek FDA approval for a special protocol assessment or SPA, to ensure the FDA’s agreement with VEN 309’s testing protocol:

We originally filed a SPA with the FDA in June 2008 to ensure their explicit agreement with our Phase III clinical plan for VEN 309. Due to lack of funds, we could not follow up or complete the process, but were able to resume with another filing in March 2010 on which we received comments in May 2010 in which the

FDA clarified their additional requirements related to the primary and secondary endpoints and recurrence. We filed another submission in July 2010 which could not be processed because the FDA required us to reformulate the questions set forth in the filing. In August and September 2010, we had a series of emails and telephone calls with the FDA in which we believe that agreement has been reached on the precise definition of the endpoints and how to assess recurrence of hemorrhoids in the study and on October 28, 2010 we filed another submission reflecting these discussions. The FDA has 45 days to respond to this submission and *we expect to complete the SPA process by the end of the first quarter of 2011.*

[Emphasis added.]

45. These statements were materially false and/or misleading when made because Ventrus did not, in fact, expect to complete the SPA process by the end of the first quarter of 2011. Instead, Defendants merely used the SPA to lure investors to the IPO, because, according to CW1, investors would misinterpret the SPA as an indication that the FDA would approve VEN 309. Rather, the SPA is simply an acknowledgement by the FDA of the testing protocol. Further evidencing the falsity and/or misleading nature of this statement, Ventrus abandoned its SPA application by July, 2011. Therefore, Defendants did not reasonably “expect to complete the SPA process by the end of the first quarter of 2011.”

46. The IPO Prospectus also stated, regarding Ventrus’ planned use of the IPO proceeds:

We intend to use the proceeds from this financing to contract with clinical research organizations, or CROs, to conduct the first of the two required Phase III clinical trials with VEN 309 in the treatment of hemorrhoids in the U.S. and Canada, using the FDA-agreed protocol under the SPA, supervised by us, and to contract the initiation of the carcinogenicity study required for the approval of VEN 309 in the U.S.

* * *

After the results of the Phase III study are available, and if we raise additional capital, *we intend to continue the carcinogenicity study, conduct the 6 and 9 month chronic toxicology studies and launch either an identical Phase III trial and a safety study, or a larger Phase III trial to provide adequate numbers of patients exposed, and to complete the clinical pharmacology program which,*

will include extensive drug-drug interaction studies to clarify the CYP2D6 interactions and a “thorough QT study” to test the arrhythmogenic potential, which studies are routinely required by the FDA. We will also explore at that time the feasibility of lifecycle options for follow-on products such as combinations with steroids and other agents or different formulations such as suppositories, which could be developed for launch after approval of the original VEN 309 product.

[Emphasis added.]

47. These statements were materially false and/or misleading when made because Defendants either knew or recklessly disregarded that the proceeds from the IPO were not intended for VEN 309 testing. The primary purpose of the IPO was to repay the Company’s creditors, pay Defendants Ellison and Barrett large salaries and bonuses, and continue Ventrus as a going concern. Although some proceeds were spent on the VEN 309 trials, Defendants were careful not to spend very much money on these trials because they had no credible data to support VEN 309’s effectiveness. For example, CW2 stated that Ventrus would not even pay to remove polyps discovered during Phase III’s attendant colonoscopies, which was a routine expenditure for these types of trials. Further, CW2 stated that Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development. Therefore, Defendants did not “intend to continue the carcinogenicity study, conduct the 6 and 9 month chronic toxicology studies and launch either an identical Phase III trial and a safety study, or a larger Phase III trial.”

48. On March 18, 2011, Ventrus issued a press release also filed with the SEC on Form 8-K that informed investors that the Company recently held a meeting with the FDA, and that as a result, Ventrus filed a revised protocol under an SPA with new, more robust definitions for efficacy endpoints for VEN 309. The press release quoted Defendant Ellison responding to the FDA’s recommendations as stating:

“[The Company is] *very pleased with the new endpoint definitions in that they*

showed considerable differences between active drug and placebo in our analysis of an earlier Phase IIB study in Germany, which has been the cornerstone of our development program. . . . In addition, we believe that the new endpoint definitions have the potential to provide a much stronger label which could further serve to encourage faster and broader adoption by physicians and by their patients who suffer the pain and discomfort of hemorrhoids.”

[Emphasis added.]

49. These statements from Ventrus and Defendant Ellison, were materially false and/or misleading because at the time they were made, Defendants knew and/or recklessly disregarded that more stringent endpoint definitions would not “provide a much stronger label” for VEN 309, but rather would make the FDA approval hurdle for the drug—the efficacy of which was entirely unproven—even higher and more unattainable.

50. Then on May 2, 2011, Ventrus issued another press release, again filed with the SEC on Form 8-K, that stated that the Company had added a third treatment arm to its Phase III VEN 309 study in response to a request from the FDA. The press release quoted Defendant Ellison discussing the FDA’s request as a positive development for VEN 309 and the Company:

*“When we analyzed our Phase IIB German study that compared Iferanserin given twice daily for 14 days, with placebo, using these endpoints, we observed that the majority of Iferanserin treated patients started their response by Day 3. **This raises the possibility that Iferanserin therapy may require a shorter duration of treatment to show adequate efficacy to stop the bleeding, itching and pain associated with hemorrhoids. . . . It’s not only good development practice to explore the possibility of a shorter treatment period as proposed by FDA’s feedback, but should this regimen prove to be effective, it could be even more acceptable to patients.**”*

[Emphasis added.]

51. These statements from Ventrus and Defendant Ellison were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded VEN 309’s inconclusive test results from the Phase IIB German study conducted by Amer. As such, Defendants knew that there was, in fact, no “possibility that Iferanserin therapy” could meet its

endpoints in a shorter duration of time, and therefore be “more acceptable to patients.”

52. Ellison’s materially false and/or misleading positive statements contained in the May 2, 2011 press release caused Ventrus’ common stock price to rise to \$19.10 on May 3, 2011 on heavy trading volume.

53. On May 11, 2011, ProActive Capital Group LLC, a company Ventrus hired to provide capital market strategy services for the Company, issued a press release announcing that Rodman & Renshaw more than doubled its price target for Ventrus, from \$12 to \$25 per share. ProActive Capital touted VEN 309’s development, stating:

Iferserin ointment has a relatively low risk of clinical development based on a well established mode of action and the Phase 2b clinical trial results achieved in Germany; which provided the basis for the design and endpoints in the upcoming clinical trial. In addition, the treatment of hemorrhoids is currently based on over-the-counter (OTC), non-prescription products and there is no FDA approved treatment for this very common condition. In addition OTC treatments such as Preparation H or Anusol do not address the underlying cause of hemorrhoids and merely treat the symptoms while Iferserin works directly on the local blood vessels that result in the condition.

[Emphasis added.]

54. These statements from Ventrus, delivered through a contracted marketing company retained to work on its behalf, were materially false and/or misleading when made because Defendants knew and/or recklessly disregarded that Phase IIB clinical trials in Germany were completely inconclusive due to the small number of participants in the study, and therefore they had no basis for saying that “Iferserin ointment has a relatively low risk of clinical development” due to Phase IIB results.

55. On June 22, 2011, Ventrus issued a press release filed with the SEC on Form 8-K announcing that the Company received a response from the FDA concerning the VEN 309 SPA. In the release, the Company stated that the FDA had “requested additional information be

included in the protocol pertaining to certain details of the trial. None of these new recommendations affect the previous recommendations made by the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design of the trial.” The press release then included the following statement from Defendant Ellison regarding the FDA’s recommendations:

"The Special Protocol Assessment process for our first pivotal trial with iferanserin (VEN 309) for the treatment of hemorrhoids has been very productive considering that this could be the first new drug application ever filed for a drug in this indication " "This process involved considerable work and thought at the FDA, and though we have not received a final agreement letter, we have implemented all of the suggestions and recommendations of the FDA on the major and important elements of the protocol, including, the definitions of the primary and secondary endpoints, overall design, regimens and doses, basic inclusion and exclusion criteria as well as overall statistical powering and the basic analysis methods. In addition, the definition of the endpoints that the FDA proposed relating to cessation, not just improvement of symptoms, and the addition the FDA proposed of the 7 day treatment are, are important enhancements to our program. Given the substantial progress that we have made with the FDA in this process, we have decided to proceed with directly implementing our protocol with all FDA recommended changes without further pursuing the SPA.

[Emphasis added.]

56. The foregoing statements were materially false and/or misleading when made because Defendants knew or recklessly disregarded that the SPA was not, in fact, “productive” with regard to FDA approval of VEN 309, as the acceptance of the FDA’s suggested definitions and endpoints only raised the bar for demonstrating the drug’s efficacy. Moreover, Ellison’s statement that the Company “decided to proceed with directly implementing our protocol with all FDA recommended changes without further pursuing the SPA” was also materially misleading because it failed to disclose that Defendants only used the SPA as a means of garnering additional investor interest in the IPO, Ellison’s statement.

57. On July 14, 2011, Ventrus filed Prospectus II in connection with its prior

Registration Statement for the sale of 4.5 million additional shares of the Company's stock at \$10.00 per share. Prospectus II continued to tout the efficacy of VEN 309 and the positive test results from previous studies:

Our product, VEN 309, an NCE formulated as an ointment for intra-anal application, has highly selective, antagonistic activity against peripheral 5-HT 2A receptors involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-HT 2A receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. *Seven clinical studies of VEN 309 have been completed, and five of these studies demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids versus placebo ointment. We believe VEN 309 has the potential to be more effective than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only currently validated treatment options.*

[Emphasis added.]

58. These statements were materially false and/or misleading when made because the only Phase II data Ventrus had that was the data from Amer, the inventor of the drug, and that data was woefully inconclusive due to the small sample sizes used in his studies. For this same reason, the Phase II trials could not have “demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids.” For the same reason, Defendants had no reason to believe VEN 309 had the “potential to be more effective than” currently available remedies.

59. Ventrus also disclosed in Prospectus II that the Company would no longer be pursuing the SPA for VEN 309:

Based on our clinical experience, we filed a Special Protocol Assessment, or SPA, with the FDA for our two proposed pivotal Phase III trials for VEN 309 for the treatment of hemorrhoids. During that process, we addressed all recommendations of the FDA to date including the definitions of the primary and secondary endpoints along with the other important design elements of the trial. *However, we have determined to not further pursue the SPA so as not to delay the start of our planned Phase III trial for VEN 309 for the treatment of hemorrhoids. We*

have begun contracting with sites for the first of the two planned pivotal Phase III trials and expect to begin the trial in the summer of 2011, complete enrollment by January 2012, and have data available in the first quarter of 2012.

[Emphasis added.]

60. In reality, Ventrus abandoned its plans to pursue the SPA because Ventrus only used the SPA as a means of garnering additional investor interest in the IPO. Therefore, the statement that the Company “chose to not further pursue the SPA” in order “not to delay the start of our Phase III trial for VEN 309” was materially false and/or misleading when made.

61. Despite Ventrus’ abandonment of the SPA application, the Company expressed to investors that the VEN 309 phase III trials were still on track:

None of these recommendations affect the previous recommendations of the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design. We have incorporated these latest changes into the protocol and, in order to maintain our timelines for the trial, we intend to file the protocol to our existing IND with the FDA, and to not continue to pursue the SPA process.

[Emphasis added.]

62. This statement was materially false and/or misleading when made because Defendants either knew or recklessly disregarded that VEN 309’s Phase II testing did not produce reliable results of efficacy and therefore Defendants knew or recklessly disregarded that VEN 309’s Phase III testing would not meet its endpoints. As stated by CW2, Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development.

63. The Company then filed its Form 10-Q financial statement with the SEC for the quarter ending June 30, 2011, in which Ventrus stated that the Phase III clinical trial for VEN 309 was on track:

We have met with the FDA regarding our plans for the development of VEN 309, VEN 307 and VEN 308. We intend to initiate and conduct one of two pivotal

Phase III clinical trials in the U.S. with VEN 309 beginning in the summer of 2011 and initiate a long term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial, which is expected in the first quarter of 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, *we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first trial, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA, which we anticipate could occur as early as 2014.*

[Emphasis added.]

64. The foregoing statements were materially false and/or misleading when made because Defendants either knew or recklessly disregarded that VEN 309's Phase II testing did not produce reliable results of efficacy and therefore Defendants knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints. As stated by CW2, Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development. Therefore, Defendants did not "intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial" nor did they intend to conduct "a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study."

65. Thereafter, on November 14, 2011, Ventrus filed its Form 10-Q financial statement with the SEC for the quarter ending September 30, 2011 in which the Company again reiterated that VEN 309's Phase III trials were on track.

We have met with the FDA regarding our plans for the development of VEN 309, VEN 307 and VEN 308 (phenylephrin). We initiated one of two pivotal Phase III clinical trials in the U.S. with VEN 309 in August 2011 and intend to initiate a long-term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial, which is expected in the first half of 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual

property estate, we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first trial, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA, which we anticipate could occur as early as 2014.

66. These statements were materially false and/or misleading when made because Defendants either knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints and therefore knew or recklessly disregarded that the Company would not "initiate a long-term carcinogenicity study." As stated by CW2, Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development. Therefore, Defendants did not "intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial" nor did they intend to conduct "a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study."

67. The same day the Company filed its 10-Q for the quarter ending September 30, 2011, Ventrus also held a conference call with analysts during which Defendant Ellison discussed the Phase III trials and confirmed that VEN 309 remained on track for further development:

NDA filing timelines for this product remain unchanged, inasmuch as these trials are not on critical path. *In addition, the data quality is good. Good clinical research practice procedures are good. And I'm happy to say that no serious severe adverse events related to the drug have been seen to date.*

[Emphasis added.]

68. Defendant Ellison's statements during the November 14, 2011 conference call were materially false and/or misleading when made because Defendants knew or recklessly disregarded that data quality was not "good." None of the participants in the VEN 309 Phase III

trial experienced the required relief from hemorrhoid symptoms to allow the trial to meet its endpoints. For this reason, it was also materially misleading "to say that no serious adverse events related to the drug have been seen to date" because the drug's total ineffectiveness was a severely adverse event relating to the drug's chances of FDA approval. Moreover, CW2 stated that she engaged in update calls with Ellison regarding the drug's trials, thus these issues were known to at least Defendant Ellison.

69. Also on November 14, 2011, Ventrus issued a press release filed with the SEC on Form 8-K regarding in which the Company announced that it extended the timing to report the top line results from Phase III trial of VEN 309 by approximately three months. With regard to the status of the clinical trials, Defendant Ellison again confirmed that the Phase III trials remained on track for future development:

"Both trials [VEN 309 and VEN 307] are progressing well with respect to data quality and GCRP (Good Clinical Research Practices). As we expect to report top line Phase 3 results for both products in the second quarter of 2012, these milestones are likely to be close together in time...." "Our projected NDA filing timelines for both VEN 309 and VEN 307 remain on track, and the new completion timelines for VEN 309 should have no material effect on the balance sheet."

[Emphasis added.]

70. The foregoing statements by Defendants were materially false and/or misleading when made for at least two reasons. First, the Company failed to disclose to investors that the reason why Ventrus delayed reporting for Ventrus' top line Phase III results until the second quarter of 2012 was because Ventrus planned to effectuate a third offering of stock to infuse the Company with capital prior to releasing the VEN 309 study results that Ventrus knew or should have known would be unfavorable. With the knowledge that VEN 309 would not meet its endpoints, Defendants knew that people would not invest in Ventrus after its lead drug candidate

failed to demonstrate efficacy in each of the 603 participants of the study. Defendants also knew or recklessly disregarded that VEN 309 was not “progressing well.” None of the participants in the VEN 309 Phase III trial experienced the required relief from hemorrhoid symptoms to allow the trial to meet its endpoints. Furthermore, the projected NDA filing deadlines for VEN 309 were not “on track” as Defendant Ellison stated, because Defendants either knew or recklessly disregarded that VEN 309’s Phase III testing would not meet its endpoints and therefore knew or recklessly disregarded that the Company would discontinue the study thereafter. As stated by CW2, Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development.

71. The November 14, 2011 press release went on to report that the Company closed its acquisition of VEN 309 with Amer, touting the commercial potential of the drug. Specifically, Defendant Ellison stated:

"Given what we have discovered about the commercial potential of VEN 309, the progress of the development program, and what we have learned about the details of the regulatory pathway and the potential market and data exclusivity, we are very pleased to be able to finalize this transaction..." ***"We believe that this could considerably enhance the value of this asset to the company."***

[Emphasis added.]

72. Defendant Ellison’s statement was materially false and/or misleading when made because Defendants knew or recklessly disregarded that the “pathway” to FDA approval was bleak, and the only reason why the Company followed through with the acquisition of VEN 309 was to continue to mislead investors until the third offering of Ventrus stock was complete. Moreover, Defendants did not, in fact, “believe that [the acquisition of VEN 309] could considerably enhance the value of this asset to the company” because they knew or recklessly disregarded the unreliability of Amer’s Phase IIB study and the poor ongoing results from the Phase III study would inevitably lead to the discontinuation of VEN 309 development.

73. Then, on January 13, 2012, Ventrus issued a press release filed with the SEC on Form 8-K announcing that the peer review journal Clinical Therapeutics published the prior Phase IIB study of VEN 309. The Company stated that the Phase IIB study demonstrated the efficacy of VEN 309:

Compared with placebo, iferanserin [VEN 309] significantly reduced patient reported severity of daily bleeding beginning at day 1 and itching beginning at day 2 ($P < 0.05$). The effects were sustained throughout the 14-day treatment period. There was also a reduction in patient-reported severity of daily pain seen with iferanserlin treatment. Adverse events were mild and infrequent and did not differ significantly between treatment groups.

[Emphasis added.]

74. The foregoing statements were materially false and/or misleading when made because Defendants knew or recklessly disregarded that this data was based upon a study that, according to CW1, Ventrus' former chief medical officer, used too few patients glean the true efficacy of the drug. Furthermore, the statement that VEN 309 "significantly reduced patient reported severity of daily bleeding at day 1 and itching beginning at day 2" was misleading in that it led investors to believe that VEN 309's Phase III endpoints would be met, despite the fact that the endpoints required a total cessation of bleeding and itching.

75. Moreover, the January 13, 2012 press release also stated that the Clinical Therapeutics publication provided an analysis of the Phase III endpoints, and that the German Phase IIB study demonstrated a satisfaction of those endpoints:

In the German Phase 2b study, it was determined that 57% of iferanserlin-treated patients had cessation of bleeding versus only 20% of placebo-controlled patients ($P = 0.0001$). The secondary endpoints of the ongoing Phase 3 study are cessation of itching and pain by day 7 through day 14. In the German Phase 2b study, the data showed that 59% of iferanserlin-treated patients versus 32% of placebo-controlled patients ($P = 0.034$) had cessation of itching, while pain ceased at day 7 and did not return by day 14 in 50% of iferanserlin-treated patients versus 18% of placebo-treated patients ($P = 0.032$).

[Emphasis added.]

76. This statement was materially false and/or misleading when made because according to CW1, Ventrus' former chief medical officer who worked alongside Defendant Ellison, the German Phase IIB study used too few patients glean the true efficacy of the drug. Therefore, relating the results of the German study to the Phase III endpoints gave investors the false impression that the German Phase IIB results would lead to a satisfaction of the Phase III endpoints.

77. The January 13, 2012 press release also included a statement from Defendant Ellison, touting the findings of the Phase IIB study:

"[t]he findings of this Phase 2b German trial were significant in defining the targeted patient population and developing meaningful endpoints for our ongoing pivotal Phase III trial for iferanserin. The therapeutic benefits observed in the Phase 2b trial suggest a potential role for iferanserin for the treatment of symptomatic hemorrhoids."

[Emphasis added.]

78. This statement from Ellison was materially false and/or misleading when made because the findings of the Phase IIB German trial were not "significant." As previously explained, because the German Phase IIB study used such a small sampling of study participants, the results of the study were unreliable and inconclusive. Therefore, the "therapeutic benefits observed in the Phase 2b trial" ***did not*** "suggest a potential role for iferanserin for the treatment of symptomatic hemorrhoids."

79. On March 14, 2012, Ventrus filed its annual report on Form 10-K with the SEC, reporting that its Phase III trial for VEN 309 remained on track and reiterated that the Phase IIB trials suggested success on the Phase III trial because the German study showed that VEN 309 "provided rapid and sustained improvements of the main symptoms of this disorder: bleeding itching and pain." Furthermore, the Company again related the German study's success at

meeting its endpoints with the endpoints of the Phase III trial:

We have modeled the potential performance of the primary and secondary endpoints which were proposed by the FDA and which we will be using in that trial, using data from the German Phase IIb trial, because ***the principal elements of the German Phase IIb trial are substantially similar to our first Phase III trial.***

[Emphasis added.]

80. This statement was materially false and/or misleading when made because the endpoints of the Phase III trial were far more stringent than those of the German Phase IIB trial. The Phase III trial required a total cessation of bleeding whereas the Phase IIB endpoints were only an improvement of symptoms. Furthermore, because the German Phase IIB study used such a small sampling of study participants, the results of the study were unreliable and inconclusive and therefore not helpful in gauging the drug's performance at the Phase III stage that included over 600 participants.

81. The 2011 10-K also described the German Phase IIB results as demonstrating statistically significant improvement of symptoms for VEN 309 over placebo:

Applying the proposed statistical methodology and primary endpoint for our Phase III trial to the data from the German Phase IIb trial, ***the difference between the proportion of patients responding to treatment as defined by the new endpoint*** definition for cessation of bleeding in the VEN 309 arm (57% responders) and the placebo arm (20% responders) ***was considerable*** with $p < 0.0001$ (Figure 4). Similarly, ***analyses of the key secondary endpoints of pain and/or itching also showed considerable differences between VEN 309 and placebo*** (itching: 59% response to VEN 309 versus 32% response to placebo, $p < 0.034$; pain: 50% response to VEN 309 versus 18% to placebo, $p < 0.032$).

[Emphasis added.]

82. Using the German Phase IIB trial results as a benchmark for the success of VEN 309 at the Phase III trial stage was materially false and/or misleading because the endpoints of the Phase III trial were far more stringent than those of the German Phase IIB trial. The Phase

III trial required a total cessation of bleeding whereas the Phase IIB endpoints were only an improvement of symptoms. Furthermore, because the German Phase IIB study used such a small sampling of study participants, the results of the study were unreliable and inconclusive and therefore not helpful in gauging the drug's performance at the Phase III stage that included over 600 participants.

83. On May 9, 2012, three weeks before the Company's third public offering, Ventrus filed its Form 10-Q financial statement for the quarter ending March 30, 2012. The financial statement maintained the Company's schedule for VEN 309 development:

Depending on our assessment of the data generated by the Phase III trial [for VEN 309], which is expected in late June or early July 2012, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, *we intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial which, together with the first study, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a new drug application, or NDA, to the FDA and analogous filings to authorities in Europe and Japan, which we anticipate could occur in 2014.*

[Emphasis added.]

84. The foregoing statements were materially false and/or misleading when made because Defendants either knew or recklessly disregarded that VEN 309's Phase II testing did not produce reliable results of efficacy and therefore Defendants knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints. At the time the Defendants issued this statement, the Company had already delayed the publication of results from its Phase III trial in order to squeeze in one more public offering to the public. These statements, made with knowledge or reckless disregard of the ineffectiveness of VEN 309, were issued as a means of drawing investors to their third offering before the inevitable publication of the devastating Phase III results. As stated by CW2, Ventrus did not wait to analyze the results from its first

Phase III study before shutting down all clinical trials of the drug and discontinuing its development. Therefore, Defendants did not “intend to initiate and conduct the second Phase III trial, and a double blind recurrence trial” nor did they intend to conduct “a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study.”

85. On May 29, 2012, less than a month prior to revealing the results of Phase III, Ventrus filed its prospectus for a third offering (Prospectus III) of approximately 948,378 shares of Ventrus stock. Prospectus III continued to mislead investors as to the efficacy of VEN 309:

Our product, VEN 309, an NCE formulated as an ointment for intra-anal application, has highly selective, antagonistic activity against peripheral 5-HT 2A receptors involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-HT 2A receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. ***Seven clinical studies of VEN 309 have been completed, and five of these studies demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids versus placebo ointment. We believe VEN 309 has the potential to be more effective than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only currently validated treatment options.***

[Emphasis added.]

86. These statements were materially false and/or misleading when made because the only Phase II data Ventrus had that was the data from Amer, the inventor of the drug, and that data was woefully inconclusive due to the small sample sizes used in his studies. For this same reason, the Phase II trials could not have “demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids.” For the same reason, Defendants had not reason to believe VEN 309 had the “potential to be more effective than” currently available remedies.

87. Prospectus III also stated that the Company “inten[ded] to”:

- complete one of two planned pivotal Phase III trials in the U.S. of VEN 309 for the treatment of hemorrhoids, that began in August 2011 and for which enrollment was completed in April 2012 and for which top-line results are expected in late June or early July 2012;
- *assuming positive data from the initial Phase III trial for VEN 309, conduct an additional pivotal Phase III trial as well as a Phase III double-blind recurrence trial.* Assuming acceptable results from these clinical trials, as well as from clinical pharmacology and other, non-clinical activities, such as carcinogenicity and toxicology studies, *prepare and file an NDA for VEN 309 for the treatment of hemorrhoids in 2014;*
- assuming VEN 309 is approved by the FDA, and because there are no FDA-approved prescription drug competitors in the U.S., we intend to *commercialize the product in the U.S. using either our own sales force or through an agreement with a suitable partner and to license the product for sale outside of the U.S.;*

88. The foregoing statements were materially false and/or misleading when made because Defendants either knew or recklessly disregarded that VEN 309's Phase II testing did not produce reliable results of efficacy and therefore Defendants knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints. As stated by CW2, Ventrus did not wait to analyze the results from its first Phase III study before shutting down all clinical trials of the drug and discontinuing its development. Therefore, Defendants did not intend to "conduct an additional pivotal Phase III trial as well as a Phase III double-blind recurrence trial," "prepare and file an NDA for VEN 309 for the treatment of hemorrhoids in 2014," or "commercialize the product in the U.S. using either our own sales force or through an agreement with a suitable partner and to license the product for sale outside of the U.S."

THE TRUTH ABOUT VENTRUS AND VEN 309 IS BELATEDLY DISCLOSED

89. On June 25, 2012, the truth emerged when Ventrus issued a press release, also filed on Form 8-K with the SEC, in which the Company announced that it would completely halt the development of iferanserin ointment (VEN 309), after the Phase III trials resulted in 603 patients—every single participant in the VEN 309 Phase III trials—failing to meet the endpoints

for improved bleeding, itching and pain assessed in the trials.

90. In particular, Ventrus disclosed that:

[Ventrus'] Phase 3, randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with hemorrhoidal disease *did not meet its endpoints.*

The Phase 3 trial randomized 603 patients to one of three, twice-daily treatment groups: 7 days of active treatment followed by 7 days of placebo, 14 days of active treatment, or 14 days of placebo treatment. Elimination of bleeding from day 7 through day 14 of treatment was the primary endpoint, with elimination of itching and pain from day 7 through day 14 as the secondary endpoints. *Results of this large, well-controlled study failed to demonstrate an improvement for therapy, in either treatment arm, over placebo for the primary and secondary endpoints.*

[Emphasis added.]

91. Furthermore, the Company announced that Ventrus would abandon the VEN 309 program in favor of its VEN 307 and VEN 308 drug candidates:

While the Company intends to analyze the totality of its Phase 3 data further, it believes that current resources would be better allocated toward the planned completion of its VEN 307 (diltiazem cream) development program in anal fissures and the beginning of further development of VEN 308 (topical phenylephrine) in fecal incontinence. *Consequently, Ventrus has no immediate plans to continue development of VEN 309, resulting in a reduction in expenses.*

[Emphasis added.]

92. The press release quoted Defendant Ellison noting that the results were unexpected, but that the Company was well-positioned to further the development of other drugs in its portfolio:

"We would like to thank both investigators and patients for their support and participation in this study and in the VEN 309 program. The outcome of our Phase 3 study comes as a surprise and a disappointment, particularly given the strong evidence of activity in our Phase 2 randomized study," said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "Despite this setback, we remain excited about our pipeline and, with a strong cash position, plan to refocus our efforts on taking VEN 307 forward toward registration as a treatment for anal fissures. VEN 307 recently

demonstrated a positive outcome in all key measures of efficacy – pain on defecation, overall pain and healing – in this indication in its first Phase 3 study. With the planned elimination of all VEN 309-related expenses, we believe the company is sufficiently capitalized to take VEN 307 through a second Phase 3 study and to approval.”

93. The revelation of the previously-concealed true facts regarding the relevance and success of Phase IIB testing, the planned use of IPO and other offering proceeds, and the overall efficacy VEN 309 eviscerated the value of Ventrus stock. After closing at \$12.26 on Friday, June 22, 2012, Ventrus shares plummeted to just \$5.02 on Monday, June 25, 2012, on abnormally high trading volume. This one-day drop of \$7.24 represented a devastating 59% decrease in Ventrus’ stock value.

94. The news regarding VEN 309 caused an evisceration of Ventrus’ stock value from which it has not recovered. As of the filing of this Complaint, Ventrus shares are trading at \$3.22 per share.

ADDITIONAL INDICIA OF SCIENTER

95. As alleged herein, Defendants acted with scienter in that they inflated the value of its stock by knowingly and/or recklessly misrepresenting the efficacy of VEN 309, the success of its previous testing, and the likelihood of FDA approval of the drug.

96. Ventrus began its operations in 2007 with the acquisition of licenses to VEN 307 (anal fissures) and VEN 308 (fecal incontinence), procured with loans made by Rosenwald and his company, Paramount Biosciences. Because anal fissures and fecal incontinence do not affect a very large percentage of people and because VEN 307 and VEN 308 were not very far along in their development, Ventrus needed an investor-friendly drug to attract the marketplace.

97. VEN 309 provided the perfect opportunity for Defendants to raise money to support the Company and themselves. VEN 309 targeted hemorrhoids, a disease that, according

to Ventrus, affects over 12 million people in the United States alone. Furthermore, there are no FDA approved treatments for hemorrhoids, which would allow Ventrus to corner the market with drug exclusivity for years. Finally, VEN 309 had previously been tested up through a Phase II study, so all Ventrus would need to do is perform a Phase III study before submitting its new drug application (NDA) with the FDA. These characteristics made VEN 309 a perfect lure for investors to infuse capital into the floundering company.

98. The Phase IIB study of VEN 309 in Germany did not demonstrate the effectiveness of VEN 309, which Defendants knew or recklessly disregarded. First, the study was conducted by Amer, the inventor of the drug. Amer had a vested interest to ensure iferanserin worked, as he could make millions of dollars licensing and eventually selling the rights to drug. Despite this conflict, Ventrus would accept his study as gospel, even though two other companies had spent the time and money to license the drug from Amer and conduct various tests, but ultimately returned the rights to iferanserin him. Second, CW1, the former chief medical officer of Ventrus who was one of Ventrus' three employees (the other two being Defendant Ellison and Dr. Dietrich) at the time, expressed concern over the small number of participants in the German Phase IIB study. Because of the small number of patients studied, the efficacy results were inconclusive and unreliable.

99. Furthermore, Defendants knew or recklessly disregarded that the endpoints of Amer's Phase IIB trials were based on the patients' own assessments of reduction in bleeding (primary endpoint) and pain, itchiness, and other sensations (secondary endpoints), and therefore far more subjective and easier to meet than the Phase III endpoints that required a complete cessation of bleeding, pain, itchiness, etc. Defendants, and particularly Defendant Ellison, discussed the relationship between the Phase IIB and Phase III endpoints in the various

prospectuses and during conference calls with analysts, but never informed investors of this important discrepancy. As a doctor and as Chief Medical Officer of Ventrus, Defendant Ellison knew or at the very least should have known the Phase IIB results were not statistically significant to the goal of meeting Phase III endpoints.

100. Defendants were also motivated to mislead investors as to the efficacy of VEN 309 and the success of the Phase IIB study. As a preliminary matter, Ventrus could not afford to develop and test VEN 307 and VEN 308 without investor support, and VEN 307 and 308 were not far enough along in their development to garner such financial support. As a result, the Company was motivated to exaggerate the Phase IIB results of VEN 309 in order to finance the development of VEN 307 and VEN 308 and continue Ventrus as a going concern.

101. Defendants Ellison and Barrett were also motivated to mislead investors regarding the success of the Phase IIB study, the efficacy of VEN 309 and the planned use of IPO and subsequent offering proceeds because Ellison and Barrett personally profited from Defendants' misrepresentations. First and foremost, Ellison and Barrett would receive bonuses directly tied to the market capitalization of Ventrus. Specifically, Ellison and Barrett would receive a bonus of \$250,000 if Ventrus' market capitalization exceeded \$100 million. Ventrus achieved this milestone in August 2011, and Ellison and Barrett received their bonuses shortly thereafter. Moreover, Ellison and Barrett would receive a bonus of \$500,000 if the Company's market cap exceeded \$250 million. Thus, the more money Ellison and Barrett raised in public offerings and the more investors were misled to believe VEN 309 would receive FDA approval, the more money Ellison and Barrett would receive in bonuses.

102. Second, because the offerings kept the Company afloat and infused tens of millions of dollars into Ventrus, Ellison and Barrett were able to pay themselves huge annual

salaries of \$375,000 and \$250,000 respectively and large annual performance bonuses. Due to the bonuses and salaries Defendants would and did receive as a result of their misrepresentations to the market, there is a strong inference that Defendants made the aforementioned false and/or misleading statements with scienter.

103. The size and manner with which Ventrus operated also raise the inference of scienter. Prior to the IPO and during CW1's tenure as Chief Medical Officer, Ventrus only had three employees: CW1, Defendant Ellison, and former President of Clinical Operations Dietrich. At the time of the IPO, Ventrus still only had three employees: Defendant Ellison, Defendant Barrett and Chief Business Officer Thomas Rowland. Thereafter, only a small handful of employees were hired during the Class Period. All clinical trials for VEN 307, 308, and 309 were performed by contract research organizations; therefore, all work performed on these drugs was performed by contractors who reported to Ventrus' small, close-knit nucleus of executives, which further strengthens the inference of scienter.

CORE OPERATIONS

104. In page 2 and 54 of the IPO Prospectus, page 47 of Prospectus II and page 1 of Prospectus III, Ventrus acknowledged VEN 309 to be Ventrus' "lead product." As Ventrus' "lead product" during the Class Period, VEN 309 and its FDA approval were of critical importance to the Company. Ventrus describes itself in its Prospectuses and 10-K SEC filings as a "developmental stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence." Prior to its IPO and the start of the Class Period, Ventrus' only business operations consisted of holding the licensing rights to three gastrointestinal drugs, because it did not even have the capital to begin phase III testing on any of the drugs. Given that Ventrus'

entire business hinged on the development of these three drugs—VEN 307, VEN 308 and VEN 309—and that VEN 309, as their acknowledged “lead product,” was the furthest developed and most marketable of the three drugs, Defendants’ knew or should have known of VEN 309’s ineffectiveness and that the Company had overstated the success of Phase I and Phase II. In fact, from the Company’s inception to December 31, 2011, Ventrus had allocated six times more resources to VEN 309 than its other drug candidates.

105. Furthermore, because Defendants Ellison (Chief Executive Officer and Chief Medical Officer) and Barrett (Chief Financial Officer) were the highest-level officers and directors of Ventrus during the Class Period, they were thus in a position to know facts of critical importance to the Company. At any given time throughout the Class Period, Ventrus employed only a very small, discrete group of employees, with whom Ellison and Barrett directly interacted.

106. By virtue of their high-level positions and the integral role VEN 309 played in the Company’s survival as a going concern, Defendants Ellison and Barrett knew or should have known the adverse facts regarding VEN 309’s efficacy that contradicted their public statements.

LOSS CAUSATION/ECONOMIC LOSS

107. By failing to disclose the efficacy of VEN 309, investors were not aware of the true value of neither Ventrus’ developmental drug portfolio nor Ventrus’ overall business plan. Therefore, Defendants presented a misleading picture of Ventrus’ business and prospects. Thus, instead of truthfully disclosing during the Class Period the true state of the Company’s business, Defendants caused Ventrus to conceal the truth from investors. Defendants’ false and/or misleading statements had the intended effect and caused Ventrus securities to trade at artificially inflated levels throughout the Class Period. However, as a direct result of the

Company's problems coming to light, Ventrus' stock value fell approximately 59% on Monday, June 25, 2012, when Ventrus announced that the Phase III trial for VEN 309 failed to meet its endpoint for nearly every single trial participant and that the Company was abandoning further development of the drug. This drop removed the inflation from the price of Ventrus securities, causing real economic loss to investors who purchased the Company's securities during the Class Period.

108. The declines in the price of Ventrus' securities after the truth came to light were a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of Ventrus' stock price decline negates any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants fraudulent conduct. The economic loss suffered by Plaintiffs and the other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of Ventrus' securities and the subsequent decline in the value of Ventrus' securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

109. The economic loss, *i.e.*, damages suffered by Plaintiffs and other members of the Class, was a direct result of Defendants' misrepresentations and omissions being revealed to investors, and the subsequent significant decline in the value of the Company's shares was also the direct result of Defendants' prior misstatements and omissions being revealed.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

110. Throughout the Class Period, the market for Ventrus stock was an efficient market for the following reasons, among others:

- a. Ventrus securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market, throughout the Class Period;
- b. As a regulated issuer, Ventrus filed periodic public reports with the SEC and the NASDAQ;
- c. Ventrus securities were followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;
- d. Ventrus regularly issued press releases, which were carried by national newswires. Each of these releases was publicly available and entered the public marketplace.

STATUTORY SAFE HARBOR DOES NOT APPLY

111. As a preliminary matter, the federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to IPOs. 15 U.S.C. § 77z2(b)(2)(D): Application of Safe Harbor for Forward-Looking Statements (“Except to the extent otherwise specifically provided by rule, regulation, or order of the Commission, this section shall not apply to a forward looking statement that is made in connection with an initial public offering.”).

112. Furthermore, the statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as “forward-looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Ventrus who knew that those statements were false when made.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

113. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Ventrus between December 17, 2010, and June 25, 2012, inclusive (the "Class") and who were damaged when the truth regarding the relevance and success of Phase IIB testing, the planned use of IPO and other offering proceeds, and the overall efficacy VEN 309 were revealed to the public, which negatively impacted the value of Ventrus securities. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

114. The members of the Class are so numerous that joinder is impracticable. Throughout the Class Period, Ventrus securities were actively traded on the NASDAQ. As of March 8, 2012, the Company had 12,406,406 shares of common stock issued and outstanding. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discover, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Ventrus or its transfer agent and may be notified of the

pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

115. Plaintiffs' claims are typical of the claims of the members of the Class as all members of each class are similarly affected by Defendants' conduct in violation of federal law that is complained of herein.

116. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.

117. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether Defendants made materially untrue and/or misleading statements/omissions during the Class Period; and

(c) the extent to which the members of the Class have sustained damages and the proper measure of damages.

118. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members is impracticable. Furthermore, as the damages suffered by individual class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

CLAIMS FOR RELIEF

COUNT I

(For Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants—Ventrus, Ellison, and Barrett)

119. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

120. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public regarding Ventrus' business, operations, management and the intrinsic value of Ventrus securities; (b) enable Defendants to inflate and maintain the artificial inflation in the price of Company stock throughout the Class Period; (c) enable Defendants to receive stock price-tied bonuses, pay the Company's creditors and continue as a going concern; and (d) cause Plaintiffs and other members of the Class to purchase Ventrus securities at artificially inflated prices, resulting in damages after the truth was revealed and the artificial inflation was removed from the price of the stock. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, jointly and individually (and each of them) took the actions set forth herein.

121. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Ventrus' securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued as primary participants in the wrongful and illegal conduct charged herein and as controlling persons as alleged below.

122. Defendants, individually and in concert, directly and indirectly, by the use, means

or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Ventrus as specified herein.

123. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Ventrus' value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Ventrus and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Ventrus securities during the Class Period.

124. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts. Such Defendants' material misrepresentations and/or omissions were done knowingly or with reckless disregard for the purpose and effect of concealing Ventrus' operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' material misstatements and omissions of the Company's business and operations throughout the Class Period, and specifically, regarding the efficacy of VEN 309, the purported success of the VEN 309's Phase IIB testing, and the Company's intentions to drop the drug's SPA, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were

reckless in failing to obtain such knowledge by recklessly refraining from taking those steps necessary to discover whether those statements were false or misleading.

125. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Ventrus' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Ventrus' publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Ventrus securities during the Class Period at artificially high prices and were damaged after the truth regarding the efficacy of VEN 309, the purported success of the VEN 309's Phase IIB testing, and the Company's intentions to drop the drug's SPA, was revealed, which removed the artificial inflation from Ventrus' stock.

126. Defendants Ellison and Barrett's primary liability arises from the following facts: (a) Defendants Ellison and Barrett were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (b) both of these Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (c) both of these Defendants enjoyed significant personal contact and familiarity with each other and were advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances and operations at

all relevant times; and (d) both of these Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

127. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Ventrus publicly traded securities. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the problems that Ventrus was experiencing, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Ventrus securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

128. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

129. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of the Company's securities during the Class Period.

COUNT II
**(For Violations of §20(a) of the Exchange Act against Individual Defendants
Ellison and Barrett)**

130. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

131. At various times during the Class Period, including at the time of issuance of the IPO and for a period of time thereafter, Defendants Ellison and Barrett were the only two

employees of Ventrus. At most, Ventrus employed only a small, intimate group of employees, and all clinical trial work was completed by contract research organizations such as LCH Clinical Research LLC, through Armonia Clinical Research.

132. Defendants Ellison and Barrett acted as controlling persons of Ventrus within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendants Ellison and Barrett had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendants Ellison and Barrett were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

133. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

134. As set forth above, Ventrus and Defendants Ellison and Barrett each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants Ellison and Barrett are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants Ellison and

Barrett wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period and the related damages resulting after the true facts were revealed and the artificial inflation was removed from the price of the stock.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

1. Determining that this action is a proper class action, certifying Lead Plaintiffs as Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' Lead Counsel as Class Counsel pursuant to Rule 23(g);
2. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
3. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;
4. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder; and
5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: September 16, 2013

Respectfully submitted,

KAHN SWICK & FOTI, LLC



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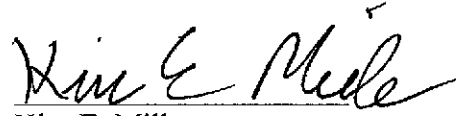
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Class*

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed on September 16, 2013 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on September 16, 2013.


Kim E. Miller